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April 9, 2014

VIA ECF (COPY BY FEDERAL EXPRESS)

Honorable Claire C. Cecchi, U.S.D.J.
United States District Court
District of New Jersey
Martin Luther King, Jr. Federal Building
& U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *In re* Biogen '755 Patent Litigation – Civil Action No. 10-2734 (CCC)(MF)

Dear Judge Cecchi:

Attached please find a corrected version of the April 8, 2014 letter to the Court that includes Exhibit 1, which was inadvertently omitted from the original filing. *See* D.E. 255. The inclusion of Exhibit 1 is the only change made to the original filing.

We thank the Court for its attention and courtesies, and if there are any questions we make ourselves available at the Court's convenience.

Respectfully,

s/Sheila F. McShane

Enclosure
cc: Counsel of Record (via ECF notice)

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April 8, 2014

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District of New Jersey
Martin Luther King, Jr. Federal Building
& U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *In re* Biogen '755 Patent Litigation – Civil Action No. 10-2734 (CCC)(MF)

Dear Judge Cecchi:

On behalf of EMD Serono, Inc. and Pfizer, Inc., we wrote on March 11, 2014 to bring to the Court's attention the Decision of the PTAB dated October 3, 2013, a copy of which is attached to our initial letter. We brought this Decision to the Court's attention as soon as we became aware of its contents, which occurred only after multiple, explicit requests to Biogen over the course of more than five months (on 10/9/2013, 10/30/2013, 1/23/2014, and 3/3/2014). We write today in response to Biogen's letters of March 21, 2014 and April 3, 2014.

The narrow but important point made in our March 11 letter was simply this: the Decision of the PTAB expressly rejected the very arguments Biogen urged at the claim construction hearing in this matter with respect to the supposed significance of the restriction requirement. Biogen's letter dated March 21, 2014 does not deny this fact, nor could it do so, and Biogen's letter of April 3, 2014 adds nothing new to the discussion. It is unfortunate that Biogen has seen our letter as an opportunity to submit lengthy, new and profoundly incorrect arguments on unrelated matters, as detailed in the March 28, 2014 Bayer letter.

We write for the sole purpose of responding briefly to certain issues newly-raised by Biogen's letters that have not yet been addressed.

- Biogen wrongly suggests that the PTAB's Decision "effectively overrid[es] the 1982 restriction requirement" as to claims directed to polypeptides. Biogen's March 21 letter, at 2. The Decision does no such thing. Biogen was unable to obtain any polypeptide claims because the PTAB expressly found that such claims were *obvious* in view of the DNA claims previously awarded to Sugano. The PTAB did *not* find that the 1982 restriction requirement was "wrong," it simply found that Biogen lost any claims to interferon beta *polypeptides* when it lost claims to interferon beta *DNA*. Nothing in the PTAB's Decision is in any way inconsistent with the Examiner's decision in 1982 requiring Biogen, as a purely administrative matter, to separately pursue its claims to

DNA, polypeptides, processes, etc. Indeed, the Decision flatly *rejects* the contrary suggestion that the restriction requirement was evidence of patentability ("this evidence [the restriction requirement] is not persuasive of patentability because restriction requirements are made for 'examination convenience,' not as a final determination on the subject matter claimed." Decision at 2.

- Similarly, Biogen wrongly suggests that it is our position that the Examiner's restriction requirement was "wrong." Indeed, Biogen goes so far as to suggest that this is the "essence of Defendants' argument." Biogen's March 21 letter, at 4. That argument has *never* been made by *any* Defendant in this case at *any* time, for the simple reason that the Examiner's 1982 restriction requirement in this case has nothing to do with the substantive claim construction arguments now at issue, for all of the many reasons identified in the Decision (as noted above) and in the Defendants' claim construction briefing. The restriction requirement is simply *irrelevant* to issues of patentability, as it is to claim construction.

- Biogen argues that it is somehow significant that the Patent Office never declared an interference as to Biogen's method of treatment claims in the '755 patent. Biogen's March 21 letter, at 4. Biogen made a similar argument to the PTAB in the latest Sugano interference, where it urged that the declaration of an interference should somehow be considered evidence of patentability. As it did with all of Biogen's positions, the PTAB squarely rejected this argument too. Decision at 3.

- Biogen argues that the *Sanofi* case can be distinguished because the verb tense of the "produced" and "transformed" limitations is somehow dispositive of whether they recite required process steps. Biogen's April 3 letter, at 2. But as Defendants have explained repeatedly in their briefs, the tense is irrelevant; process limitations are routinely expressed in the past tense, *see, e.g.*, D.I. 116 at 11, including in the *Monsanto* case that controls the outcome here, *see* D.I. 239 at 7 (citing *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1355 (Fed. Cir. 2007)). Furthermore, Biogen's reliance on the fact-bound ruling of *Amgen* is misplaced, (*see* D.I. 119-1 at 11) as is Biogen's effort to ignore the clear import of representations Biogen made to the Patent Office to procure the '755 patent.

- Finally, Biogen notes that Dr. Goeddel and Genentech initially sought a claim to the use of recombinant interferon-β. Biogen's April 3 letter, at 2. What Biogen fails to tell the Court is that Dr. Goeddel *withdrew* that claim (Exhibit 1 at 2), and thus, by the time the Patent Office declared its first interference regarding interferon-β applications, no other treatment claim was pending and no interference *could* have been declared as to such claims.

In sum, the Decision makes clear that the 1982 restriction requirement is irrelevant to the claim construction issues in this case, contrary to what Biogen has previously told this Court. The Decision also provides further, significant evidence of invalidity by confirming that the claims of the '755 patent are directed to treating a patient with *a polypeptide invented by Sugano*, produced using *a DNA sequence invented by Sugano*.

We thank the Court for allowing us to be heard on this matter.

Respectfully,

s/Sheila F. McShane

cc: All Counsel (via ECF notice)

Exhibit 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

DAVID V. GOEDDEL
and ROBERTO CREA

Art Unit 123
Examiner B. Hazel

Serial No. 291,892, filed August 11, 1981

For: MICROBIAL PRODUCTION OF MATURE HUMAN FIBROBLAST INTERFERON

RESPONSE TO RESTRICTION REQUIREMENT

Nutley, New Jersey 07110
October 21, 1982

Honorable Commissioner of Patents & Trademarks

Washington, D.C. 20231

S i r:

This is in response to the Office Action dated September 21, 1982. In the Office Action, restriction has been required among the following groups of claims:

Group I. Claims 1-4, drawn to polypeptides, classified in Class 260, subclass 112.5R.

Group II. Claims 5 and 6, drawn to DNA sequence, classified in Class 536, subclass 27.

Group III. Claim 7, drawn to microbial expression vehicle, classified in Class 435, subclass 172.

Group IV. Claims 8, 9, 11 and 12, drawn to microorganism, classified in Class 435, subclass 253.

Group V. Claim 10, drawn to plasmid, classified in Class 435, subclass 172.

Group VI. Claims 13-16 and 18, drawn to compositions and method of use, classified in Class 424, subclass 85.

Group VII. Claim 17, drawn to a cell culture, classified in Class 435, subclass 240.

Group VIII. Claims 19-21, drawn to a process, classified in Class 435, subclass 172.

Group IX. Claims 22 and 23, drawn to a process, classified in Class 435, subclass 172.

Applicants hereby elect to prosecute the claims of Group I, i.e., claims 1-4. This election is made without traverse and without prejudice to applicants' right to pursue the subject matter of the non-elected claims in divisional applications.

The Examiner is hereby authorized to call the undersigned attorney of record "collect" on any matter connected with this application. The telephone number is Area Code 201, 235-5194. In the absence of the undersigned attorney of record, the call will be accepted by any other attorney empowered in this application.

Respectfully submitted,

Attorney for Applicants

Peter R. Shearer (Reg. No. 28117)
340 Kingsland Street
Nutley, New Jersey 07110

PRS:cjg

I hereby certify that this correspondence is being deposited with the United States Postal Services as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D. C. 20231, on

October 21, 1982